Health Advisory:

Actavis Recalls Remaining Fentanyl Patches in the U.S.

March 6, 2008

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Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

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Health Advisory
March 6, 2008

FROM: **JANE DRUMMOND**
DIRECTOR

SUBJECT: **Actavis Recalls Remaining Fentanyl Patches in the U.S.**

Due to the serious nature of potential consequences of use and the extended expiration dates of the product, DHSS would like to alert health care providers, facilities, and pharmacies of an expanded recall of Fentanyl patches.

Summary:

Actavis Inc., the United States manufacturing and marketing division of the generic pharmaceutical company Actavis Group hf, announced on March 1, 2008, that its subsidiary Actavis South Atlantic LLC is proceeding with the voluntary recall from wholesalers and pharmacies of all lots of Fentanyl transdermal system CII patches sold in the United States.

This recall is an expansion of the Company's initial recall of 14 lots of Fentanyl transdermal patches announced on February 17, 2008. That recall was due to the identification of a possible fold-over defect present in the product that potentially could cause leakage of the fentanyl gel. The remaining lots of Fentanyl transdermal system patches are being recalled as a precautionary measure because Actavis lacks assurance that all patches are free from defects.

All of the recalled patches were manufactured by Corium International Inc., a contract manufacturer for Actavis, and sold nationwide in the United States.

Fentanyl patches sold by Actavis in Europe are not affected by this recall.

Background:

As per the approved product labeling for Fentanyl transdermal system, fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are leaking or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. Anyone who comes in contact with fentanyl gel should thoroughly rinse exposed skin with large amounts of water only; do not use soap. Immediately dispose of affected patches that may be damaged or compromised in any way by flushing them down the toilet, using caution not to handle them directly. Damaged and/or compromised patches that have leaked gel will not provide effective pain relief.

Please note: Actavis South Atlantic LLC was formerly known as Abrika Pharmaceuticals Inc. The pouches containing the patches may be labeled with an Abrika Pharmaceuticals label, but the outer carton bears the Actavis logo with the following product names:

Actavis Fentanyl Transdermal System, 25 mcg/hr. NDC 67767-120-18.
Actavis Fentanyl Transdermal System, 50 mcg/hr. NDC 67767-121-18.
Actavis Fentanyl Transdermal System, 75 mcg/hr. NDC 67767-122-18.
Actavis Fentanyl Transdermal System, 100 mcg/hr. NDC 67767-123-18.

The lots covered by this recall have expiration dates between May 2009 and December 2009. Anyone who has Fentanyl patches labeled with an Abrika or Actavis label should check them for these expiration dates.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Fentanyl transdermal system is indicated for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time and cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate release opioids.

Lots Being Recalled

Lot	Exp. Date	NDC	Strength
27540	Aug 09	67767-120-18	25mcg/hr
27584	Aug 09	67767-120-18	25mcg/hr
27666	Sep 09	67767-120-18	25mcg/hr
27759	Oct 09	67767-120-18	25mcg/hr
27611	Oct 09	67767-120-18	25mcg/hr
27762	Oct 09	67767-120-18	25mcg/hr
27761	Oct 09	67767-120-18	25mcg/hr
27832	Nov 09	67767-120-18	25mcg/hr
27747	Nov 09	67767-120-18	25mcg/hr
27758	Nov 09	67767-120-18	25mcg/hr
27903	Dec 09	67767-120-18	25mcg/hr
27573	Sep 09	67767-121-18	50mcg/hr
27576	Sep 09	67767-121-18	50mcg/hr
27667	Oct 09	67767-121-18	50mcg/hr
27668	Oct 09	67767-121-18	50mcg/hr
27581	Oct 09	67767-121-18	50mcg/hr
27763	Oct 09	67767-121-18	50mcg/hr
27751	Nov 09	67767-121-18	50mcg/hr

27586	Aug 09	67767-122-18	75mcg/hr
27572	Sep 09	67767-122-18	75mcg/hr
27582	Oct 09	67767-122-18	75mcg/hr
27583	Oct 09	67767-122-18	75mcg/hr
27745	Oct 09	67767-122-18	75mcg/hr
27746	Oct 09	67767-122-18	75mcg/hr
27539	Aug 09	67767-123-18	100mcg/hr
27574	Sep 09	67767-123-18	100mcg/hr
27575	Sep 09	67767-123-18	100mcg/hr
27577	Sep 09	67767-123-18	100mcg/hr
27578	Oct 09	67767-123-18	100mcg/hr
27579	Oct 09	67767-123-18	100mcg/hr
27580	Oct 09	67767-123-18	100mcg/hr
27610	Oct 09	67767-123-18	100mcg/hr
27612	Oct 09	67767-123-18	100mcg/hr
27743	Oct 09	67767-123-18	100mcg/hr